UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.*	
[UNDER SEAL],	**Civil Action No. 17-5736-PD**
Plaintiff,	**AMENDED COMPLAINT**
v.	
[UNDER SEAL],	**FILED *IN CAMERA* AND UNDER SEAL**
Defendant.	

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA and THE STATES OF CONNECTICUT, FLORIDA, INDIANA, MARYLAND, MICHIGAN, NEW JERSEY, NEW YORK, VIRGINIA, and WASHINGTON, D.C., *ex rel.* JANE DOE,	**Civil Action No. 17-5736-PD**
Plaintiff,	**JURY TRIAL DEMANDED**
v.	**FILED *IN CAMERA* AND UNDER SEAL**
CENTER FOR VEIN RESTORATION (MD), LLC AND SANJIV LAKHANPAL, MD.	NOT TO BE POSTED ON PACER
Defendant.	

AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

1. This *qui tam* action is brought by Plaintiff and Relator Jane Doe to recover treble damages and civil penalties, on behalf of the United States of America and various States under the False Claims Act, 31 U.S.C. §§ 3729-33, as amended, and analogous State statutes against Defendants Center for Vein Restoration (MD), LLC ("CVR" or "Defendant") and Sanjiv Lakhanpal, MD, FACS, the founder and CEO of CVR (collectively, "Defendants").

2. Defendants are engaged, individually, jointly and severally, in the business of treating varicose veins and venous insufficiency. There are more than 70 CVR clinics located in 13 states, including Alabama, Connecticut, Florida, Indiana, Maryland, Virginia, Connecticut, Michigan, New Jersey, New York, Ohio, Pennsylvania and Washington, D.C.

3. Defendant CVR is a provider in the Medicare program, and agreed to be bound by the conditions imposed on them by the federal law and regulations.

4. From at least 2009 to the present, and prior, based on information and belief and the Defendants' known practices, Defendants have intentionally and knowingly billed and submitted, or caused to be billed and submitted, false claims to Government healthcare programs, including, but not limited to, Medicare, Medicaid and TRICARE/CHAMPUS, and private insurers.

5. Many of Defendants' patients receive their service as beneficiaries of Government healthcare programs, including, but not limited to, Medicare, TRICARE/CHAMPUS, and other government-funded healthcare programs.[1]

Parties

6. Relator Jane Doe is an adult citizen of the United States and has resided in Maryland during the time relevant to this action.

7. Relator worked for Defendant Center for Vein Restoration (MD), LLC as an ultrasound technician from 2008 through December 2014. Because Relator served as a "floater" for part of that time, she observed similar misconduct, as described below, at several CVR locations.

8. Defendant Center for Vein Restoration (MD), LLC ("CVR") was formed as a Maryland limited liability company in 2011 and is headquartered in Greenbelt, Maryland.

9. Defendant CVR is a medical clinic that provides outpatient health care services to treat venous insufficiency, a condition affecting the ability of veins to send blood from the legs to the heart, commonly known as and referred to herein as varicose veins. CVR claims it is the nation's largest physician-led vein treatment medical center.

[1] Medicare, Medicaid and various Veteran Affairs programs (*i.e.*, TRICARE) are collectively referred to as "Government Healthcare Programs."

10. There are more than 70 CVR clinics located in 13 states, including Alabama, Connecticut, Florida, Indiana, Maryland, Virginia, Connecticut, Michigan, New Jersey, New York, Ohio, Pennsylvania and Washington, D.C. CVR maintains a website at www.centerforvein.com.

11. Defendant CVR advertises on its website that it accepts Medicare and Medicaid and that its costs are currently covered by Medicare and Medicaid.

12. Defendant Sanjiv Lakhanpal, MD, FACS, is the President and CEO of Defendant CVR. Dr. Lakhanpal is a cardiovascular surgeon.

13. Dr. Lakhanpal is the founder of Defendant CVR and manages the day-to-day operations and determines the policies and practices of CVR at each of its locations. Dr. Lakhanpal directs the physicians, treaters and staff of CVR at each of the company's locations, including to perform the practices complained of herein.

Jurisdiction, Venue. Filing and Service

14. This Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. § 1345 in that the Relator brings this action in the name of the United States, and 31 U.S.C. §3732 which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Under 31 U.S.C. §3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Amended Complaint.

15. Personal jurisdiction and venue are proper in this court pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. §3732, as one or more defendants are found in, resides in, have or had an agent or agents, have or had contacts, and transact or transacted business, or have or had committed any act proscribed by 31 USCS § 3729 in this District.

16. The Relator has provided the federal government with a disclosure of substantially all material evidence and information related to the information in this Amended Complaint during a meeting with federal agents in 2017 and again in April 2018 during a meeting with lawyers from the U.S. Attorney's Office for the Eastern District of Pennsylvania and the U.S. Attorney's Office for the District of Maryland, as well as government investigators.

17. This Amended Complaint is being filed under seal pursuant to 31 U.S.C. §3730(b)(2).

Applicable Law

A. The False Claims Act

18. The False Claims Act provides, in pertinent part:

(a) Liability for Certain Acts.—

(1) In general.— Subject to paragraph (2), any person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

* * * * *

(3) Costs of civil actions.— A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) Definitions.— For purposes of this section—

(1) the terms "knowing" and "knowingly"—

(A) mean that a person, with respect to information—

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud;

(2) the term "claim"—

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—

(I) provides or has provided any portion of the money or property requested or demanded; or

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property;

(3) the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

(4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

19. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 28 C.F.R. § 85.1, False Claims Act civil penalties were increased from $5,000 to $11,000 for violations occurring on or after September 29, 1999.

B. The Federal Anti-Kickback Statute

20. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(A) and (B), prohibits offering to pay or paying any remuneration to any person to induce such person "to purchase . . . any good . . . service, or item for which payment may be made in whole or in part under a federal healthcare program" or "to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program."

21. Pursuant to the Anti-Kickback Statute, it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product or service (including diagnostic services) for which payment is sought from any federally-funded health care program,

including Medicare, Medicaid and TRICARE. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), *cert denied*, 474 U.S. 988 (1985). In order to ensure compliance, every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the Anti-Kickback Statute and other federal laws governing the provision of health care services in the United States.

22. A violation of the Anti-Kickback Statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Any party convicted under the Anti-Kickback Statute must be excluded from federal health care programs for a term of at least five years. 42 U.S.C. § 1320a-7b. The government may also assess civil money penalties, which could result in treble damages plus $50,000 for each violation of the Anti-Kickback Statute. 42 U.S.C. § 1320a-7a(a)(7).

23. Importantly, although the Anti-Kickback Statute does not afford a private right of action, the federal False Claims Act provides a vehicle whereby individuals may bring *qui tam* actions alleging violations of the Anti-Kickback Statute. *See* 31 U.S.C. §§ 3729 *et seq*.

24. Compliance with the Anti-Kickback Statute is required for reimbursement of claims from federal health care programs, and claims made in violation of the law are actionable civilly under the FCA. 42 U.S.C. § 1320a-7b(g) (2010) (stating, in part, that a "claim that includes items or services resulting from a violation of . . . [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the FCA]. . . ."); *see also United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 315 (3d Cir. 2011) (stating "[c]ompliance with the AKS is clearly a condition of payment under Parts C and D of Medicare" and holding that "appellants,

by alleging that appellees violated the AKS while submitting claims for payment to a federal health insurance program, have stated a plausible claim for relief under the FCA.").

25. The Anti-Kickback Statute was amended in March 2010 as part of the Patient Protection and Affordable Care Act ("PPACA"), which clarified that all claims resulting from a violation of the Anti-Kickback Statute are also a violation of the FCA. 42 U.S.C. § 1320a-7(b)(g). The PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." Public Law No. 111-148, § 6402(h).

26. Proof on an explicit *quid pro quo* is not required to show a violation of the Anti-Kickback Statute.

C. State False Claims Acts

27. This action also arises pursuant to the following analogous provisions of state and local law:

Connecticut False Claims Act, Chapter 319v § 17b-301a *et seq.*
Florida False Claims Act, Fla. Stat. § 68-081 *et seq.*
Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.*
Maryland False Claims Act, Md. Code Ann., Health-Gen. § 2-601 *et seq.*
Michigan Medicaid False Claims Act, Mich. Comp Laws Serv. § 400.601 *et seq.*
New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq.*
New York False Claims Act, N.Y. St. Fin. Law § 187 *et seq.*
Virginia Fraud Against Taxpayers Act, Va. Code § 8.01-216.1 *et seq.*
District of Columbia False Claims Act, D.C. Code § 2-308.13 *et seq.*

STATUTORY AND REGULATORY BACKGROUND

A. Medicare

28. The Medicare program was created in 1965 as part of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, to provide a federally funded health insurance program for the aged and

disabled. The United States, through HHS, administers the program, and has delegated the administration of the Medicare Program to Centers for Medicare & Medicaid Services, a component of HHS. Another component of HHS, the Office of Inspector General ("OIG"), is responsible for investigating Medicare fraud and abuse, as well as issuing regulations and instructions that implement the Medicare and Medicaid fraud and abuse authorities.

29. The Centers for Medicare & Medicaid Services ("CMS") is a branch of the U.S. Department of Health and Human Services. CMS is the federal agency that administers the Medicare program and monitors the Medicaid programs offered by each state.

30. The Medicare program consists of two basic parts - Part A (42 U.S.C. §§ 1395c - 1395i-5) and Part B (42 U.S.C. §§ 1395j - 1395w-4).

31. Part A of the Medicare Program covers all inpatient hospital services and post-hospital nursing facility care to eligible persons, known as Medicare beneficiaries. In addition, Part A covers certain home health services provided to Medicare beneficiaries who do not have Part B coverage.

32. Part B of the Medicare Program, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, both inpatient and outpatient, diagnostic services and durable medical equipment as long as the services are medically necessary.

33. Medicare makes payments under Part A and Part B using private companies and insurance companies ("contractors") which provide these services under a contract with the Health Care Financing Administration ("HCFA"). These companies pay Medicare claims and determine the amount of reimbursable costs based on coverage and reimbursement policies established by

HCFA. The companies are also responsible for identifying fraud and abuse under guidelines established by the OIG.

34. Medical treatment and services by physicians that are reimbursable under the Medicare Part B and Medicaid Programs must be reasonable and medically necessary. The physician or entity seeking reimbursement, including Defendants herein, must meet certain obligations to participate as a Medicare provider, including the following duties to:

a. Bill for only reasonable and necessary medical services. 42 U.S.C. § 1395y(a)(1)(A);

b. Not make false statements or misrepresentations of material facts concerning;

c. Requests for payment. 42 U.S.C. § 1320a-7b(a)(1) & (2); 1320a-7; 1320a-7a;

d. Provide economical medical services, and then, only where medically necessary. 42 U.S.C. § 1320c-5(a)(1);

e. Provide evidence that the service given is medically necessary. 42 U.S.C. § 1320c-5(a)(3);

f. Assure that such services are not substantially in excess of the needs of such patients. 42 U.S.C. § 1320a-7(b)(6) & (8);

g. Not submit or cause to be submitted bills or requests for payment substantially in excess of the physician's usual charges for the same treatment or services. 42 U.S.C. § 1320a-7(b)(6)(A);

h. Certify when presenting a claim that the service provided is a medical necessity. 42 U.S.C. § 1395n(a)(2)(B).

35. Medicare and Medicaid specifically exclude from reimbursement "any expense incurred for items or services where such expenses are for cosmetic surgery or are incurred in connection therewith." 42 U.S.C. § 1395y(a)(10).

36. The Social Security Act provides that no Medicare payment may be made for items and services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury . . . ." 42 U.S.C. § 1395y(a)(l)(A). Accordingly, to lawfully bill Medicare for services, the

documentation regarding such services must adequately establish reasonableness and medical necessity.

37. Physicians submit claims to Medicare, Medicaid, and TRICARE on HCFA 1500 claims form. HCFA 1500 requires the physician's signature certifying that "the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction."

38. The Part B program is funded by premiums paid by Medicare beneficiaries enrolled in the program and is supplemented from funds provided and paid by the United States.

39. The Part B pays claims for reimbursement submitted by Medicare beneficiaries for a portion of reasonable charges of certain medical services that are determined to be reasonable and necessary under certain provisions of the Social Security Act.

40. CMS determines the types of services covered and reimbursable. The types of services covered must correlate to the appropriate medical condition in which the service is being provided.

B. Medicaid And Other Government Healthcare Programs

41. Medicaid is a federal health insurance system that is administered by the states and is available to low-income individuals and families who meet eligibility requirements determined by federal and state law (herein referred to as "Medicaid beneficiaries" or "Medicaid recipients"). Medicaid pays for items and services pursuant to plans developed by the states and approved by HHS through CMS. 42 U.S.C. § 1396a(a)-(b). States pay health care providers according to established rates, and the federal government then pays a statutorily established share of "the total amount expended . . . as medical assistance under the State plan." *See* 42 U.S.C. § 1396b(a)(1).

42. States electing to participate in the Medicaid program must comply with the requirements imposed by the Social Security Act and regulations of the secretary of HHS. States

participating in the Medicaid program created various state Medicaid programs, waiver programs, and the like, which reimbursed healthcare practitioners, healthcare facilities, home healthcare agencies, and/or healthcare plans for rendering Medicaid-covered services to Medicaid beneficiaries.

43. In addition to the Medicaid programs set forth above, the U.S. Department of Veteran Affairs ("Veteran Affairs"), through various programs, reimburses healthcare practitioners, healthcare facilities, home healthcare agencies and/or healthcare plans for rendering Veteran Affairs-covered services to eligible veterans and their eligible dependents.

44. Similarly, CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces.

45. Like Medicare, TRICARE and other federal healthcare benefit programs cover only medically necessary inpatient and outpatient cure. TRICARE defines "medically necessary care" as services or supplies provided by a hospital, physician, and/or other provider for the prevention, diagnosis, and treatment of an illness, when those services or supplies are determined to be consistent with the condition, illness, or injury; provided in accordance with approved and generally accepted medical or surgical practice; not primarily for the convenience of the patient, the physician, or other providers; and not exceeding (duration or intensity) the level of care, which is needed to provide safe, adequate and appropriate diagnosis and treatments. *See* http://usfhp.net/members/member-handbook/.

SPECIFIC ALLEGATIONS RELATED TO DEFENDANTS' MISCONDUCT AND FRAUD

46. Varicose veins are abnormally large veins that bulge under the skin, usually in the legs. They can be painful for many people, whether they are walking or staying still. Many

treatment recommendations exist on how to reduce associated leg swelling and discomfort, including surgical options. For medical billing purposes, these procedures are assigned codes defined by the AMA CPT® coding system.

47. Physicians at Defendant CVR ("CVR physicians") commonly treat varicose veins via Endovenous Laser Therapy ("EVLT"), also referred to as laser ablation therapy, or Radiofrequency ablation ("RFA").

48. Medicare guidelines requires that certain medical necessity is met before treatment will be reimbursed.

49. Providers may seek payment from Medicare for services rendered, but may only be reimbursed by Medicare or Medicaid for providing health care services that are certified as being "reasonable and necessary." 42 U.S.C. § 1395y(a)(1).

50. A large percentage of patients treated at Defendant CVR receive coverage through Government Healthcare Programs, including Medicare.

51. Defendant CVR generates a portion of its revenue through billing patients for services not provided, inadequately provided or not medically necessary.

52. Medical necessity is certified by the physician on the Form CMS 1500 when seeking reimbursement. Physicians indicate medical necessity by documenting the diagnosis made by the physician and the corresponding ICD-9-CM code. ICD-9 is an acronym standing for the Internal Classification of Disease, 9th Edition, the coding system currently recognized by CMS for the purpose of reimbursements.

53. Nurses at CVR would meet with the patient and perform a medical history.

54. Technicians such as Relator would then meet with the patient and perform a "vein-specific" medical history. Often, no matter what Relator or other ultrasound technicians

reported, CVR physicians would indicate that the patient had met the criteria for medical necessity for vein treatment, even if the patient had not.

55. Moreover, ultrasound technicians were ordered by Dr. Lakhanpal to make as many "positive" diagnoses as possible, even in cases where no procedure was medically necessary, in order to increase the number of procedures performed and consequently the number of claims submitted to Government Healthcare Programs for reimbursement.

56. Similarly, patients frequently should have been instructed to attempt other, often more conservative, treatment methods (i.e., compression socks) to resolve the underlying medical issues and varicose veins, but CVR physicians would not instruct the patients to attempt other treatments. Moreover, CVR physicians would falsely record on the patient's medical records that the patient had tried these other treatments, even if the patient had not.

57. This incidence of misconduct commonly arose when a patient was referred to CVR from a primary care physician who would not have recognized or treated the underlying medical issue.

58. From at least 2008 and continuing through 2014, Defendant CVR, often under the direction of and instructed by Defendant Dr. Lakhanpal, employed a variety of fraudulent billing and medical practice schemes which were intended to defraud the government:

a. Permit a surgical technician to start a procedure without a physician present;

b. Performing procedures by unqualified personnel while the physician is out of the office.

c. Unnecessary vein injections (sclerotherapy) for the treatment of varicose veins and spider veins.

d. Virtually every patient had sclerotherapy added to their treatment plan. Defendants would invent symptoms, even if the patient was not interested in cosmetic outcome.

e. Unnecessary ultrasound imaging procedures as part of vein treatment.

f. Upcoding treatments to receive more money than Medicare the Government would pay if the procedure was billed to them as performed.

g. Performing medically unnecessary vein ablation procedures.

h. Utilizing unsafe and unauthorized treatment methods (i.e., nitroglycerin paste, warming saline in microwave ovens) to artificially dilate veins in order to perform unnecessary procedures.

A. CVR Physicians Would Routinely Choose To Treat Patients With Laser Ablation, Rather Than Radiofrequency Ablation (RFA), Because Costs Were Lower For Laser Ablation But Reimbursement Was Higher For RFA

59. The Endovenous Laser Therapy ("EVLT"), or laser ablation therapy, procedure entails the insertion of a heated laser fiber into the target vein via a catheter. The physician then gradually increases the fiber's temperature until reaching the required temperature. The fiber is then removed, which collapses the vein and shut off circulation through it. The vein then slowly dies off, and blood is diverted through the remaining healthy veins.

60. Defendants obtained reimbursement for EVLT and RFA procedures rendered to patients insured through Government Healthcare Programs.

61. Both RFA and EVLT are "minimally invasive" procedures that treat venous insufficiency of the large superficial veins (the greater and lesser saphenous veins, specifically). These are the veins that are the usual source of varicose veins.

62. Unlike older surgical-based techniques, laser ablation does not involve any incision and a RFA procedure requires only a minimal incision; both procedures generally require minimal recovery time.

63. CVR performs ablation procedures in the office, rather than in an operating room.

64. Both the laser and RFA procedures use thermal energy in the form of laser or radiofrequency energy to close the blood vessel from the inside, so that the refluxing or

failing vein is no longer functional. The closed vein eventually is absorbed by the body. The "removal" of the failing vein reduces patient symptoms by decreasing venous pressure in the leg.

65. RFA uses radiofrequency energy in 20-second bursts via a tiny catheter inserted into the vein.

66. This energy targets the collagen in the vein wall. Targeting the vein wall causes the vein to shrink around the catheter as the vein is being treated. The vein, therefore, actually closes as the treatment is administered.

67. After RFA, the vein is smaller and thicker, and it no longer carries blood through it. With time, the vein actually gets absorbed by the surrounding tissues and disappears.

68. In laser ablation/EVLT, CVR physicians use a laser filament which includes a heating element that is variable.

69. EVLT is a procedure which must be performed only by licensed physicians.

70. While laser devices are designed to target the vein wall, the strong energy can cause collateral damage and can occasionally puncture the vein wall, causing leakage of blood out of the blood vessel and extensive bruising.

71. Laser ablation does not cause shrinkage of the blood vessel, but rather causes clot formation in the blood vessel, which then causes the vessel to occlude (block the flow of blood).

72. Laser ablation is often associated with more lingering pain than RFA.

73. Both methods have a very high rate of success (closure of the vein) and both are considered superior to traditional surgical methods, including "vein stripping". The main difference is that laser ablation is generally associated with more bruising, pain, and discomfort compared to RFA.

74. CVR physicians often choose to perform laser ablation, rather than RFA, for a number of reasons, including that EVLT is faster and easier to perform, even if RFA is the better and safer treatment for the patient.

75. Even though CVR physicians may perform EVLT procedures, CVR bills the procedure to Government Healthcare Programs as if the patient received a RFA procedure. In addition, although the medical chart, or operating note, for the patient would state that the physician performed a RFA procedure, the doctor would actually have performed an EVLT procedure.

76. Reimbursement is greater for RFA.

77. Besides the reimbursement rate, EVLT requires CVR to expend less hard costs then RFA.

78. Upon information and belief, CVR ships unused (but billed for) RFA supplies (*i.e.*, catheters) to India.

79. Defendants generate millions of dollars annually performing EVLT/laser ablation procedures and billing as if the CVR physician had performed RFA procedures.

80. Medicare, Medicaid and private carriers reimburse treaters for medically necessary treatment of varicose veins, which generally excludes treatment for cosmetic purposes.

81. Defendants seek reimbursements from Medicare, Medicaid and other Government Healthcare Programs, including TRICARE, as well as private carriers, for services provided to patients.

B. Defendants Managed, Directed And Participated In, And Continue To Manage, Direct And Participate In, In Other Schemes And Frauds On Government Healthcare Programs

82. Several of the physicians who participated in the various misconduct and improper procedures described above and below included, but were not limited to, Defendant Dr.

Lakhanpal; Khanh Q. Nguyen, DO, RPVI; Vinay Satwah, DO, FACI; and Sean K. Stewart, MS, MD.

83. Relator raised concerns about various misconduct at CVR to her Director at CVR (Zayed Meadows), but nothing was done to halt the wrongdoing. Meadows is now the Corporate Director of Vascular Lab at CVR.

84. Relator specifically recalls reporting the following:

- Dr. Stewart's misconduct;
- Procedures not being billed properly;
- Medically unnecessary procedures being performed by CVR physicians;
- Ultrasound technicians being instructed by CVR management to scan patients multiple times until they located potential issues that the physician could claim required treatment; and
- The enormous number of procedure being performed per day.

85. CVR physicians routinely directed non-physicians and non-trained and non-credentialed staff members to guide procedures when the CVR physician was not present in the office.

86. For example, CVR physicians would often schedule 20-25 appointments in one day, which would require surgical technicians and/or other CVR employees to begin or finish procedures so that CVR physicians could complete the number of procedures scheduled.

87. Similarly, CVR physicians and staff would routinely substitute the name of a physician for another physician who actually performed the procedure if the physician actually rendering services was not eligible for reimbursement from insurance.

88. Relator often witnessed CVR physicians creating and implementing treatment plans that were unnecessarily lengthy.

89. For example, a patient would only require four (4) treatments, but CVR would draft a plan for seventeen (17) treatments.

90. Often, as part of this unnecessarily extended treatment plan, CVR physicians would perform a treatment on a vein that had already been treated, but CVR would bill as if a new vein had been treated.

91. Relator would occasionally inform a CVR physician that a vein had already been closed and advise the physician to move to another vein, but the CVR physician would ignore her assistance and perform an unnecessary procedure on a vein already treated.

92. Additionally, physicians would often perform EVLT procedures on secondary veins, when the procedures had not been approved by ultrasound technicians for surgery and were not medically necessary.

93. Relator routinely observed CVR physicians putting improper pressure on patients to agree to the CVR physician's suggested treatment plans. The CVR physicians would imply, among other things, that not treating the varicose veins was "dangerous" to the patient's health.

94. Defendants knowingly and intentionally sterilized and reused medical instruments necessary to perform the EVLT procedures, despite the fact that the instruments used are being manufactured for five-time use only. Dr. Lakhanpal reused instruments and instructed other CVR treaters they were required to do so, also.

95. For example, CVR physicians would often use a one-time catheter more than once.

96. CVR physicians use laser fibers to perform EVLT procedures. The fibers are intended for either one-time, five-time or six-time use. Relator primarily recalls CVR physicians utilizing five-time or six-time fibers to perform the EVLT procedures.

97. Dr. Lakhanpal was using, and ordering other CVR physicians and CVR technicians to use, laser fibers that were indicated for five-time use many more times than five. Relator is aware that these fibers were sterilized by using extreme heat and a sterilization solution and often used more than a dozen times before being disposed.

98. Relator witnessed CVR physicians and technicians re-sterilize five-time use laser fibers and reuse them multiple times.

99. Over the course of several sterilizations of the one-time use fibers, the fibers became less effective, requiring additional procedures to be performed in following sessions, that would not have otherwise been necessary.

100. At least one of the surgical technicians (Shauna Gunther) recognized this was improper and posted a bulletin from the laser company stating that fibers should only be used once. That bulletin was subsequently taken down by CVR management without explanation.

101. The re-use of EVLT instruments is dangerous – i.e., fiberglass portions of the fibers become brittle and increase the risk the fiber will shatter inside a patient's veins. The efficacy of the instrument also declines upon every reuse, increasing the error rate for the procedure thus necessitating additional procedures to achieve the same intended outcome.

102. Moreover, Medicare reimbursement for performing the EVLT procedure includes reimbursement for the five-use laser fiber. However, these additional procedures are billed to the Government Healthcare Programs as if they were performed on new veins using new laser fibers.

103. By sterilizing and re-using the fibers, CVR was able to obtain and/or inflate claims for payments from Government Healthcare Programs as "new" fibers, which but for the false statements, would not have been paid.

104. CVR, by and through Dr. Lakhanpal and other CVR physicians, knowingly and intentionally submitted claims for reimbursement to Government Healthcare Programs, for procedures performed as if using the new instruments when in fact they were reusing instruments. This fraudulent maximization of federal reimbursement resulted in higher income and other payments to each Defendant and in failed procedures requiring follow-up EVLT treatments that would not have been necessary had proper medical procedure been followed by the CVR Defendants.

105. Accordingly, all reimbursement claims submitted to Medicare, Medicaid and/or private insurers, for procedures performed using sterilized and/or re-used laser fibers were improper and fraudulent.

106. The great saphenous vein (GSV) is a large, subcutaneous, superficial vein in the leg. It is the longest vein in the body running along the length of the leg. The great saphenous vein has a number of tributary veins. CVR physicians would often treat each tributary separately and bill for each treatment, even if the tributary did not require treatment.

107. Dr. Lakhanpal ordered ultrasound technicians to make as many "positive diagnoses" as possible, even in cases where no procedure was medical necessary, in order to increase the number of claims that could be submitted for reimbursement, including to Government Healthcare Programs.

108. If CVR ultrasound technician did not recommend a "positive diagnosis," indicating a need for surgery, then CVR physicians would often order the ultrasound technician to examine the patient again and "search harder", or have the patient return to the office for a re-scan with a different ultrasound technician.

109. Dr. Lakhanpal's wife, Joan Cantero-Lakhanpal, MD, is an endocrinologist who refers patients to CVR.

110. Also, Dr. Lakhanpal and his wife own an office building, and lease part of the space for a CVR clinic. Upon information and belief, that building is located at 108 Forbes Street, Annapolis, Maryland.

111. Upon information and belief, CVR had a referral agreement or arrangement with Righttime Medical Care, a string of urgent care clinics in Maryland. Righttime has approximately 15 clinics in Maryland.

112. Righttime would send any patient with leg issues or pain to a CVR clinic, even if no identified medical issues. For example, on one occasion, Righttime referred a young woman to CVR even though the patient only had a broken ankle. Righttime instructed the patient to have a scan done. Relator refused to perform the scan as it was not medically necessary.

113. Similarly, CVR has an improper referral arrangement with an entity known as the Center for Vascular Medicine ("CVM").

114. Although CVR patients did not require medical treatment at CVM, CVR physicians would refer CVR patients to CVM. Similarly, CVM physicians would refer CVM patients to CVR without cause.

115. Upon information and belief, CVM and CVR share the same ownership. For example, Dr. Lakhanpal is the founder and CEO of CVM.

116. Relator was aware that CVR physicians would instruct ultrasound technicians to use various methods to artificially increase the size of veins (dilate the veins) and manufacture venous insufficiency, including, but not limited to, applying "nitroglycerin paste" (an ointment often used to increase blood supply to the heart), heating a patient's saline bags in the clinic's

microwave, increasing the temperature in the exam room and/or simply making the patient stand for no reason other than to put pressure on the leg. Relator recalls these methods being discussed during meetings of CVR's ultrasound technicians.

117. Relator alleges that Defendant Dr. Lakhanpal, Dr. Nguyen, Dr. Stewart, and Zayed Meadows were all aware of these methods.

118. CVR physicians were offered monetary bonuses by CVR for performing more procedures.

119. Specifically, CVR offered monetary incentives to its physicians based on the number of procedures performed and billed.

120. For example, upon information and belief, the CVR physician's bonus structure had several elements, including the number of new patients seen by a physician, the number of new patients scheduled for procedures, and the number of procedures actually performed.

121. The clinics' staffs also had a bonus scale system. If the office met established numbers (quotas) required for the month in various categories, the office and its staff would receive a cash bonus from CVR to split.

122. During the time that she was employed at CVR, Relator is aware that CVR and Dr. Lakhanpal compiled data on the number of procedures performed by CVR physicians. Upon information and belief, the data was needed to determine "incentives" for physicians and the clinics.

123. Additionally, some of the doctors in various CVR offices would tell their staff that if the office performed a certain amount of procedures, the physicians would treat the office to a meal at an upscale restaurant or a dinner cruise.

124. CVR required front desk personnel to track patients and contact the patients after a certain period of time had elapsed to make appointments for additional EVLT procedures to be performed. Upon information and belief, front desk personnel were instructed to ignore whether the EVLT procedures were medically necessary when attempting to solicit patients for additional appointments and procedures.

125. Finally, CVR management would schedule events called free venous screenings where CVR personnel would perform a brief scan on individuals who approached the table or booth.

126. The CVR personnel were instructed to inform individuals that they had venous disease and refer them to a CVR office. If there were no ultrasound technicians available or willing to go to these events, CVR management would instruct a marketing representative with no medical training to attend and pretend to be an ultrasound technician. The majority of these patients did not have venous insufficiency, yet they were advised to schedule an appointment and visit CVR for examinations based on results of the screening. Insurance paid for the unnecessary scans.

127. Relator served as a "floater" for part of her employment at CVR; thus, she observed similar misconduct, as described above, at several CVR locations.

128. Relator routinely participated in company-wide conference calls with other CVR technicians where similar misconduct, as described above, was discussed.

COUNT I
False Claims Act
31 U.S.C. §3729(a)(1)
Presenting False Claims
(Against All Defendants)

129. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

130. Through the acts described above, Defendants and their agents, employees and co-conspirators has knowingly presented or caused to be presented to the United States Government false or fraudulent claims for payment or approval.

131. As a result of these false claims, the United States Government has been damaged and continues to be damaged in an amount to be determined at trial.

132. Defendants presented or caused to be presented these claims with actual knowledge of their falsity, or in deliberate ignorance or reckless disregard that such claims were false.

133. By reason of the violation of 31 U.S.C. §3729(a)(1), Defendants recklessly damaged the United States Government in as yet undetermined amount.

COUNT II
False Claims Act
31 U.S.C. §3729(a)(2)
Presenting False or Fraudulent Records
(Against All Defendants)

134. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

135. Defendants made, used or caused to be made or used, false records of statements to get false or fraudulent claims paid or approved by the United States government.

136. By reason of the violation of 31 U.S.C. §3729(a)(2), Defendants knowingly or recklessly damaged the United States Government in as yet undetermined amount.

COUNT III
Connecticut False Claims Act, Conn. Code § 17b-301b *et seq.*
(Against All Defendants)

137. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

138. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Code § 17b-301b *et seq.*

139. Upon information and belief, there is at least one CVR facility/clinic in Connecticut.

140. By virtue of the illegal acts, including the payment of commissions and to its sales representatives and improper submission of bills to various Government Healthcare Programs for equipment, supplies and services, as described more fully above, Defendants knowingly presented or caused to be presented to the Connecticut Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

141. The Connecticut Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

142. By reason of these payments, the Connecticut Medicaid Program has been damages, and continues to be damaged in a substantial amount.

COUNT IV
Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*
(Against All Defendants)

143. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

144. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq*.

145. Upon information and belief, there is at least one CVR facility/clinic in Florida.

146. By virtue of the illegal acts, including the payment of commissions and to its sales representatives and improper submission of bills to various Government Healthcare Programs for equipment, supplies and services, as described more fully above, Defendants knowingly presented or caused to be presented to the Florida Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

147. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendants, paid for claims that otherwise would not have been allowed.

148. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT V
Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5
(Against All Defendants)

149. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

150. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5.

151. Upon information and belief, there are five CVR facilities/clinics in Indiana.

152. By virtue of the illegal acts, including the payment of commissions and to its sales representatives and improper submission of bills to various Government Healthcare Programs for equipment, supplies and services, as described more fully above, Defendants knowingly presented

or caused to be presented to the Indiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

153. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendants, paid for claims that otherwise would not have been allowed.

154. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT VI
Maryland False Claims Act, Md. Code Ann. § 2-601 *et seq.*
(Against All Defendants)

155. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

156. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act of 2010, Md. Code Ann. § 2-601 *et seq*.

157. Upon information and belief, there are 17 CVR facilities/clinics in Maryland. Upon information and belief, CVR claims that an address in Greenbelt, Maryland (7300 Hanover Avenue) is the company's headquarters.

158. By virtue of the illegal acts, including the payment of commissions and to its sales representatives and improper submission of bills to various Government Healthcare Programs for equipment, supplies and services, as described more fully above, Defendants knowingly presented or caused to be presented to the Maryland Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

159. The Maryland Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendants, paid for claims that otherwise would not have been allowed.

160. By reason of these payments, the Maryland Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT VII
Michigan Medicaid False Claims Act, MCLA § 400.601
(Against All Defendants)

161. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

162. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claims Act, MCLA, §§ 400.601.

163. Upon information and belief, there are 7 CVR facilities/clinics in Michigan.

164. By virtue of the illegal acts, including the payment of commissions and to its sales representatives and improper submission of bills to various Government Healthcare Programs for equipment, supplies and services, as described more fully above, Defendants knowingly presented or caused to be presented to the Michigan Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

165. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendants, paid for claims that otherwise would not have been allowed.

166. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT VIII
New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq.*
(Against All Defendants)

167. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

168. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq*.

169. Upon information and belief, there are 12 CVR facilities/clinics in New Jersey.

170. By virtue of the illegal acts, including the payment of commissions and to its sales representatives and improper submission of bills to various Government Healthcare Programs for equipment, supplies and services, as described more fully above, Defendants knowingly presented or caused to be presented to the New Jersey Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

171. The New Jersey Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendants, paid for claims that otherwise would not have been allowed.

172. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT IX
New York False Claims Act, N.Y. State Fin. Law § 187
(Against All Defendants)

173. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

174. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law § 187.

175. Upon information and belief, there are 4 CVR facilities/clinics in New York.

176. By virtue of the illegal acts, including the payment of commissions and to its sales representatives and improper submission of bills to various Government Healthcare Programs for equipment, supplies and services, as described more fully above, Defendants knowingly presented or caused to be presented to the New York Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement.

177. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendants, paid for claims that otherwise would not have been allowed.

178. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT X
Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*
(Against All Defendants)

179. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

180. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-21 6.1 *et seq.*

181. Upon information and belief, there are 10 CVR facilities/clinics in Virginia.

182. By virtue of the illegal acts, including the payment of commissions and to its sales representatives and improper submission of bills to various Government Healthcare Programs for equipment, supplies and services, as described more fully above, Defendants knowingly presented or caused to be presented to the Virginia Medicaid Program false or fraudulent claims for payment

or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

183. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendants, paid for claims that otherwise would not have been allowed.

184. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XI
District of Columbia False Claims Act, D.C. Code § 2-308.14 *et seq.*
(Against All Defendants)

185. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

186. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act, D.C. Code 5 2-308.14 *et seq.*

187. Upon information and belief, there are 2 CVR facilities/clinics in Washington, D.C.

188. By virtue of the illegal acts, including the payment of commissions and to its sales representatives and improper submission of bills to various Government Healthcare Programs for equipment, supplies and services, as described more fully above, Defendants knowingly presented or caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

189. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendants, paid for claims that otherwise would not have been allowed.

190. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

Relief Requested

Wherefore, Plaintiff United States of America and Relator Jane Doe pray for judgment entered against Defendants as follows:

a. In an amount equal to treble (three times) the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each violation of 31 U.S.C. § 3729 prior to November 2, 2015;

b. In an amount equal to treble (three times) the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $10,781.00 and not more than $21,563.00 for each violation of 31 U.S.C. § 3729 after November 2, 2015, pursuant to 81 Fed. Reg. 42491, 42494 (Jun. 30, 2016).

c. That Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act;

d. That Relator and the U.S. Government be awarded all costs of this action, including attorneys' fees and expenses;

e. All interest relating to those amounts identified above; and

f. For such other and further relief as this Court may deem proper;

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Relator demands a jury trial for all claims and issues so triable.

Respectfully submitted,

Dated: July 17, 2018

Brian J. McCormick, Jr., Esquire
Robert Ross, Esquire
Joel J. Feller, Esquire
Matthew A. Casey, Esquire
Ross Feller Casey, LLP
One Liberty Place
1650 Market St., 34th Floor
Philadelphia, PA 19103
215-574-2000
bmccormick@rossfellercasey.com

Attorney for Relator Jane Doe